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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,691	11/29/2001	Joon Shik Shin	0662-0163P	9800

2292 7590 07/15/2003

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EXAMINER

KRISHNAN, GANAPATHY

ART UNIT PAPER NUMBER

1623

DATE MAILED: 07/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/995,691

Applicant(s)

SHIN ET AL.

Examiner

Ganapathy Krishnan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 is/are allowed.
- 6) ☒ Claim(s) 2-4 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

The Amendment A filed April 25, 2003 has been received, entered into the record and carefully considered. The following information provided in the amendment affects the instant application:

1. Claims 1-4 have been amended.
2. Remarks drawn to rejections under 35 U.S.C. 101, 112 and 103.

Claims 1-4 are pending.

Claim Rejections - 35 USC § 101

The rejection of Claim 1 under USC 101 has been overcome by amendment.

Claim Rejections - 35 USC § 112

The 112 first paragraph rejection of claim 1 has been overcome by amendment.

The 112 second paragraph rejections of claims 1-4 made in the previous office action have been overcome. New rejections are made as contained herein below.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 and 3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2 and 3 recites the terms "estrogen receptor modulator", "isotonic agent" "diluent", "lubricant" and "solubilizing aid" without particularly or distinctly providing chemical names or structures applicant intends such terms to represent. In the absence of

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a specific chemical name or structure it is not clear what substances are encompassed by these terms. The claims are rendered indefinite in all occurrences such terms are not sufficiently distinctly claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The rejections of Claims 1-3 under USC 103 have been overcome. However, Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kikuchi et al (Chem. Pharm. Bull. 1983, vol. 31, no. 7, pp. 2296-2301) is maintained for the reasons of record and for the reasons set forth herein below.

Applicant's argument regarding the rejection of claim 4 over Kikuchi et al has been considered but is not found to be persuasive.

Claim 4 is drawn to a process for making compound of formula (I) wherein R₂ is hydrogen and which is obtained by hydrolysis of compound of formula (I) wherein R₂ is cinnamoyl group and R₁ is a hydrogen or alkyl group.

Kikuchi et al teach the preparation of a compound of formula (I) wherein R₂ is hydrogen by the hydrolysis of a compound where R₂ is p-coumaroyl group (see pg. 2297, first paragraph, lines 6-7, hydrolysis of compound 3 to afford 1, Chart 1 and page 2300, the paragraph entitled Alkaline Hydrolysis of 8-O-(p-Coumaroyl)-harpagide(3)). The

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difference between the prior art and the instant invention is that the compound of the instant claim 4 contains a cinnamoyl group to be hydrolyzed. In compound 3 of the reference a coumaroyl group (group has a hydroxy substitution in the benzene ring) is hydrolyzed. The process yields the same product, namely harpagide (structure 1) whether a cinnamoyl or a coumaroyl group is hydrolyzed. Structure 1 of Kikuchi et al is a glucoside. Even though compound 3 of Kikuchi is similar to the one as instantly claimed one of ordinary skill in the art can see that the hydrolysis of compound 3 of Kikuchi gives the same compound as instantly claimed. Hence it is obvious to use the same process as Kikuchi et al to prepare the compound as instantly claimed. Since the instant claim is a process claim the use of harpagide for osteoporosis is of little to no patentable importance.

Claims 1-3 drawn to a method of treating osteoporosis, arthritis and ruptured disc comprising administering compound of formula I and a pharmaceutical composition containing formula I are neither taught nor fairly suggested in the prior art of record.

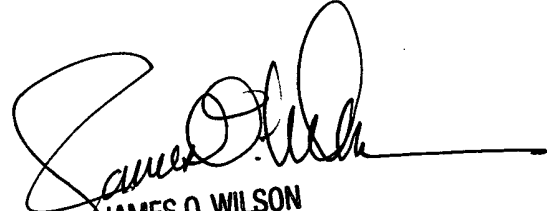
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 703-305-4837. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

GK
July 14, 2003



JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600